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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,570	02/06/2002	Vitaly Vodyanoy	35721/243744 (5721-18)	6923

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EXAMINER	
CHEU, CHANGHWA J	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 08/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,570	VODYANOY ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 23-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election on group I, claims 1, 6-19 with traverse and requested join group I and II for examination on January 6, 2004 has been received and considered. Examiner agrees with the reasoning for joining group I and II for examination. Thus, group I and II are rejoined for examination.

Applicant cancelled claims 20-22 and added claims 23-25.

Currently, claims 1-19, 23-25 are under examination.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-19, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, step (b), "preparing said peptide to be coupled to a sensor" is vague and indefinite. It is not clear what steps are needed for preparing the peptides to couple to the sensor.

With respect to claim 1, step (e), quantifying "the signal output" lacks antecedent basis.

With respect to claim 3, step (b), "an aqueous subphase" is vague and indefinite. It is not clear what constitutes "subphase."

With respect to claim 3, step (d), " a desired surface pressure" is vague and indefinite. It is not clear what applicant meant "desired."

With respect to claim 17, line 3, "the prior round of screening" lacks antecedent basis. Similarly, claim 19 shares the same problem.

With respect to claim 18, step (a), "in vivo screening", is vague and indefinite. It is not clear which of the following steps corresponding to this "in vivo screening" and what active steps should one skilled in the art to undertake accomplishing the purported purpose.

With respect to claim 18, it is not clear what kind of "sensor" applicant refers to.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 8, 9, 14, 15, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Hengerer et al. (Biosensor & Bioelectronics 1999 14: 139).

Hengerer et al. disclose an immunosensing system based on a quartz crystal bicrobalance (QCM), such as acoustic sensors on piezoelectric crystals vibration to detect target molecules in a sample (See Abstract). Hengeer et al. teach using phage library technique to identify peptides of interest (See Section 2.2 Biological Model System). Hengerer et

al. teach coupling (e.g. immobilized) the peptides of interest on the surface of the sensor for detecting corresponding ligands (page 140, second paragraph). Hengerer et al. also teach using biotin-streptavidin system to produce a stable peptide layer preparing for immobilization on the sensor (See Section 2.3 Immobilization Procedure) where the sensor is prepared (e.g. pretreated with acetone to remove component disturbing the coupling process) for subsequent coupling process (See page 140, right column, Section 2.3). The bindings are compared between methods of ELISA and QCM which include quantifying the signals output from the sensors (See Figures 1-6).

5. Claims 1, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Suleiman et al. (Analyst, 1994 119: 2279).

Suleiman et al. teach using an immuosensor, e.g. piezoelectric device, to detect target molecules in a sample (See Abstract). Suleiman et al. teach coupling (e.g. immobilizing) peptides of interest (e.g. antigen) through amide linkage, on the sensor surface to detect its binding partner antibody (i.e. ligand) in a test sample. (page 2280, right column, first paragraph) The sensor is treated (e.g. prepared) with 1-3 di(trifluoromethyl)benzene to increase binding to the protein (page 2279, right column, last paragraph). The bindings of ligand to the peptides of interest can be quantified by the output signals from the sensors (See Figures 1 and 2).

6. Claims 1-4, 14-15,23-24 are rejected under 35 U.S.C. 102(a) as being anticipated by Pathirana et al. (Biosensors & Bioelectronics 2000 15: 135).

Pathirana et al. teach coupling (e.g.immobilized) a polycolonal antibody (e.g. peptides of interest) on a quartz crystal acoustic wave device to detect bacteria Salmonella typhymurium (i.e. corresponding ligand) (See Abstract). The bindings of bacteria to the peptides can be quantified by the output signals from the sensors. (See Figures 4, 5 and 6)

With respect to claims 2-4, Pathirana et al. teach coating (e.g. preparing) phospholipids on a Langmuir-Blodgett film as a monolayer for peptide immobilization (See Section 2.6.1 Surface technique and Section 2.6.2.1 Phospholipid Monolayers). Furthermore, Pathirana et al. teach using 2% volatile organic solvent ethanol for deposition of the phospholipids. Supra. The monolayer was formed on the air-liquid interface by allowing the spreading solution to run down an inclined wettable planar surface that is partially submersed, e.g. 90-170 degrees, into the subphase. (See Figure 1 and Section 2.6.2.1) The flow rate down the plate was maintained at about 0.1 ml/min with a constant surface compressing pressure of 23 mN/m. (Section 2.6.2.1)

7. Claims 1, 8, 9 are rejected under 35 U.S.C. 102(a) as being anticipated et al. by Birkert et al. (Analytical Biochem. 2000 282: 200).

Birkert et al. teach an immunoassay for detecting binding of a ligand on a Reflectometric interference spectroscopy sensor (RIfs) where peptides of interest, e.g. antigen, can be immobilized on the surface of the sensor for interaction of the binding partner antibody. (See page 200, right column, second paragraph; page 201, left column, first paragraph; Figure 1). Birkert et al. teach using biotinylation on the peptides of interest. (See page 201, left column, second paragraph to the first paragraph on the right column). The signals of the RIfs sensor indicate the changes of thickness on the surface and reflect the degree of binding affinity (See Figure 4-8).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pathirana et al. in view of Birkert et al.

Pathirana et al. reference has been discussed but is silent in using biotinylation coupling with the peptides of interest. Birkert et al. teach that using the biotin molecules can enhance coupling of the peptides to the surface of the sensor. (See Abstract; page 202, left column, Section Preparation of Biotin Surface) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Pathirana et al. with the method of biotinylation on the peptides as taught by Birkert et al. in order to increase the efficiency of immobilization of the peptides of interest on the sensor surface for detection purposes.

11. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hengerer et al. in view of Ebato et al. (Anal. Chem. 1994 66: 1683).

Hengerer et al. reference has been discussed but is silent in teaching use of a spacer. Ebato et al. disclose that using a spacer in the Langmuir-Blodgett film can increase coupling of the target molecules to the phospholipids (See Abstract; Figure 1 and 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Hengerer with the spacer technique as taught by

Ebato et al. because such a modification teaching would motivate an ordinary skilled one in the art to adapt in order to increase the sensitivity of the assay.

12. Claims 5, 10-13, 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pathirana et al. in view of Samoylova et al. (Muscle & Nerve 1999 April, page 460).

Pathirana et al reference has been discussed but is silent in use of (1) a specific peptide ASSLNIA as recited in claim 5, SEQ ID No. 1 and (2) in vivo screening of potential ligands. Samoylova et al. disclose a muscle-specific peptide of interest, i.e. ASSLNIA, can enhance in vivo skeletal and cardiac muscle binding (See Abstract and Method). Samoylova et al. also use phage library encoding the peptides of interest for in vivo screening candidate ligands in mice model (See Figure 3 and Abstract). The phage selected process includes several rounds of passing phage expressing peptides (See page 462, third paragraph in Results, and Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have motivated Pathirana et al. to incorporate the muscle-specific ASSLNIA peptide to the sensor surface to screen candidate muscle-specific binding ligands with reasonable expectation of success because it has been shown that ASSLNIA is a muscle-specific peptides and it can enhance binding of ligands to the muscle tissues.

With respect to claims 12-13, applicant recites using at least two animal species, including human tissues. Samoylova et al. review that a "large variety of both inherited and acquired diseases affect the ability of muscle to perform" raises concern in clinical and pharmaceutical communities (See page 460, Introduction section, left column). It would have been obvious to motivate one skilled in the art at the time when invention was made to apply the invention to screen ligand in the human muscle tissue, such as cardiac or skeletal muscles associated with muscular pathogenesis, with reasonable expectation of success because applying to other animal species, i.e. human tissues, involves routine practice when the necessary techniques are available.

Conclusion

13. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner
Art Unit 1641

July 14, 2004

LONG V. LE
SUPERVISORY PATENT EXAMINER
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07/23/04